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07/542,232 06/21/90 DEUEL

T 07-24 (688) A

EXAMINER

GUEST, S

ART UNIT

PAPER NUMBER

1812

DATE MAILED:

10/28/91

SCOTT J. MEYER - A3SD  
MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD.  
ST. LOUIS, MO 63167

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 8-22-91 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                  |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-7 are pending in the application.

Of the above, claims 1-3 are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.

3. ☐ Claims \_\_\_\_\_ are allowed.

4. ☒ Claims 4-7 are rejected.

5. ☐ Claims \_\_\_\_\_ are objected to.

6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

The following rejections are withdrawn in light of applicant's amendment and arguments filed in paper number 6: 1) the rejection made under 35 USC 101 in regards to non-statutory subject matter, and 2) the rejection made under 35 USC 112, 1st paragraph in regards to the deposit requirement.

The rejection made under 35 USC 103 is maintained for the reasons stated below and in the last office action.

Applicant's election with traverse of group II, claims 4-7 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that since the DNA sequences of claims 4-7 encode the protein sequences of claims 1-3, it would be most convenient, efficient and logical, and would result in a savings of cost and time to both the PTO and applicant to join the two groups. Applicant further states that this is desirable because it is well-known that the PTO has a large backlog of biotechnology applications.

This is not found persuasive because the protein product as claimed can be made by other and materially different processes of making than by encoding the DNA of claims 4-7, such as by other conventional purification techniques or combinations of other purification techniques including, ion exchange chromatography, hydrophobic interaction chromatography, thiophilic adsorption chromatography, immunoaffinity purification techniques, ultrafiltration, density gradient ultracentrifugation, reverse-phase HPLC and/or other

conventional purification techniques. A product being made by other materially different processes of making is the requirement provided by the statute. The Office cannot subvert the statute, or merely ignore it for cost reasons or because of the backlog of applications.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-7 are rejected under 35 U.S.C. 103 as being unpatentable over Bohlen (EP 0326075) or Rauvala (EMBO J., 1989) et al. in view of Maniatis et al.. Applicants' have argued that the claimed protein is isolated from entirely different biological starting materials than used by the prior art. Applicant's have also argued that the prior art reference only teaches the NH2 terminal sequence, and therefore the instant DNA sequences are not enabled. Applicant's arguments have been fully considered but they are not deemed to be persuasive. The starting materials are not relevant in this case, because it was well known in the art at the time the invention was made that proteins, especially the general class of heparin binding proteins, are highly homologous between species and tissue type. It would have been entirely obvious to attempt to isolate a known protein from different tissue types and even different species. Furthermore, the NH2 sequence taught by the prior art is identical to the instant NH2 sequence, and therefore it would be entirely expected that the prior art sequence used as a genetic probe would have hybridized to applicant's desired DNA sequence. For these reasons, it would have been obvious to clone the instant gene sequences since the cloning procedures are used in the manner taught by the prior art for the purposes taught by the prior art. One would have been motivated to ~~clone~~ clone the HGBF

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gene since the N-terminal sequence of the purified protein had been determined and published.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shelly Guest whose telephone number is (703) 308-3154. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

The location of the art unit in which this application is being handled has been changed. To aid in the correlation of papers, future papers should be marked "Art unit 1812".

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with

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the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 308-4227.

*[Signature]*  
sjg

October 24, 1991

*[Signature]*  
DAVID L. LACEY  
SUPERVISOR PRIMARY EXAMINER  
ART UNIT 189A  
1812  
10/24/91

"obvious to try" standard usually occurs when

"...invention is made by varying all parameters or trying each of numerous choices until successful without indication in prior art as to which parameters were critical or which choices were likely to be successful, or when invention is made by exploring promising new technology or general approach with only general guidance from prior art as to particular form of claimed invention or how to achieve it."

It is asserted that neither of these cases holds true for the instant invention. There is definitely expectation of success in cloning the HBGF gene based on the amino acid sequence data in the primary references and the knowledge of the art at the time of appellants' filing. The motivation is stated above. Also, it was known that HBGF was related to FGF, and several reasonable predications can be made based on this knowledge. FGF is widely expressed in many tissues, is a fairly abundant protein, and is very homologous among mammalian species. One would expect the same for HBGF, and therefore probing many different tissue types and species would not be necessary and success in finding the HBGF DNA would be expected.

Finally, appellants point to differences in the full amino acid sequence of HBGF-8 published by Rauvala after appellants' filing date and the claimed protein sequence, now withdrawn. The differences amount to 4 of 168 amino acids, which is a 2.4% difference. This is very small and could be explained by many factors, such as experimental error, tissue differences, or species differences. Furthermore, this difference would not have affected the skilled artisan's ability to clone the HBGF gene based on the general knowledge in the art and the cited references.

For the above reasons, it is believed that the rejections should be sustained.

*David L. Lacey*  
DAVID L. LACEY  
SUPERVISORY PATENT EXAMINER  
GROUP 180  
5/12/92

Respectfully submitted,

*Shelly J. Gies*  
Shelly J. Gies